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(54) **DEVICE AND METHOD FOR ATTACHMENT OF A STOMAL SLEEVE**

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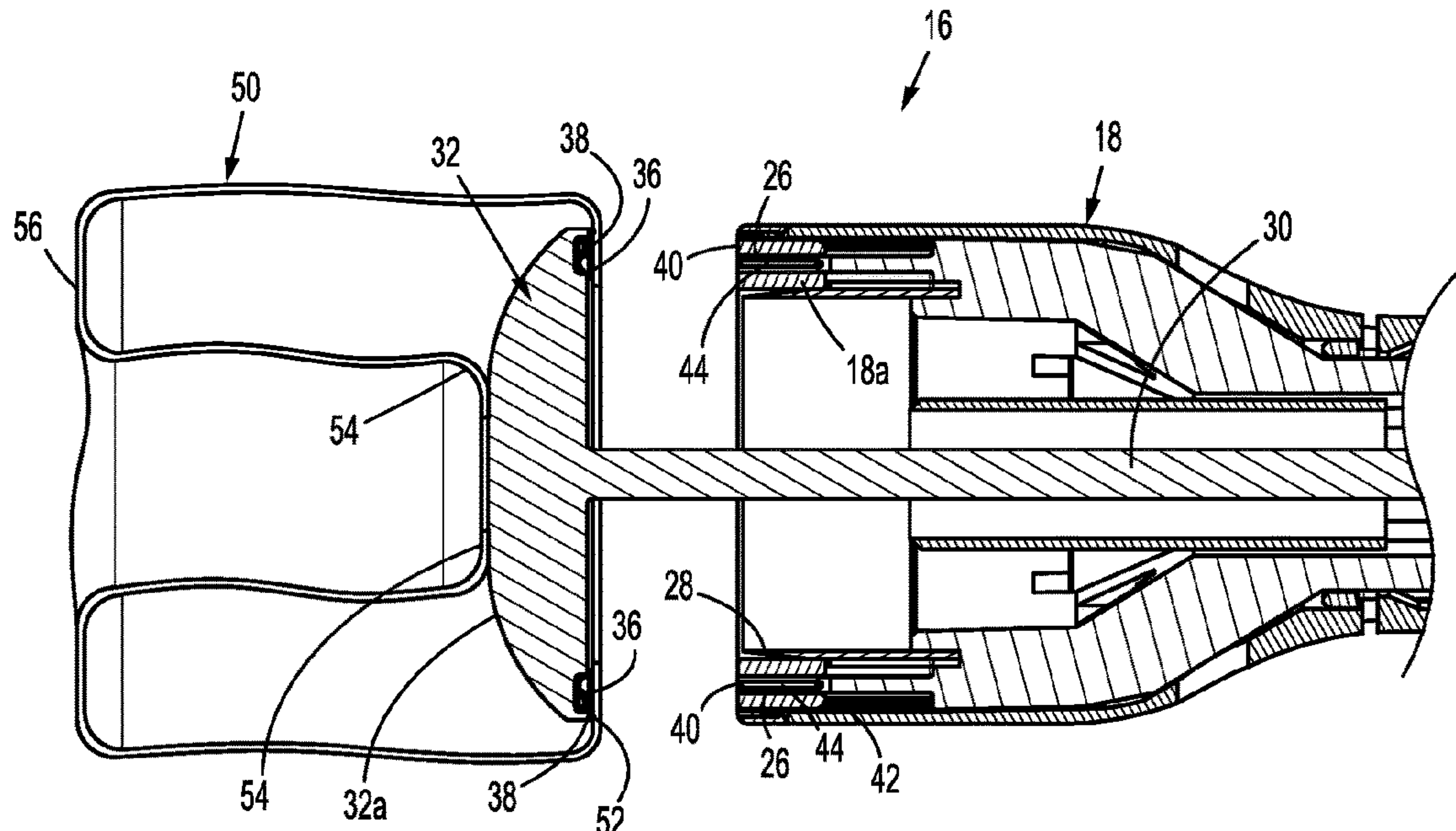
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(57) **ABSTRACT**

The presently disclosed stapling device includes a stomal sleeve secured to an anvil assembly of a tool assembly of the stapling device. The stomal sleeve has a tubular configuration having a first end portion secured to a tissue contact surface of the anvil assembly and a second end portion secured to a distal face of an anvil head of the anvil assembly. In use, the stapling device is fired to secure the first end portion of the stomal sleeve to dermal and intestinal tissue within a stoma and to separate the first end portion of the stomal sleeve from the anvil assembly. When the stapling device is withdrawn from the stoma, the second end portion of the stomal sleeve is withdrawn from the stoma and subsequently disengaged from the anvil head of the anvil assembly such that the second end portion of the stomal sleeve is positioned externally of the stoma.

**7 Claims, 8 Drawing Sheets**





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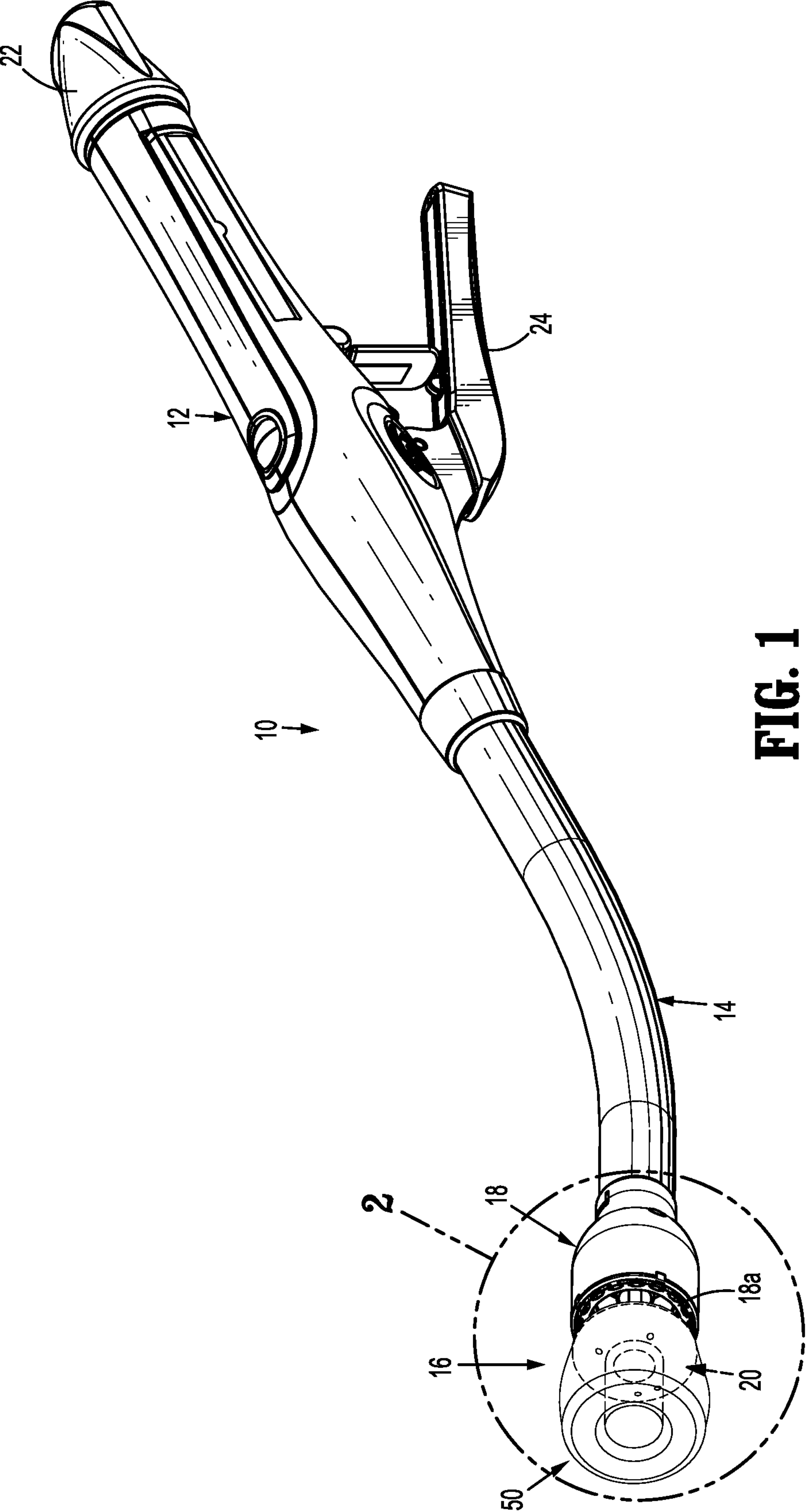
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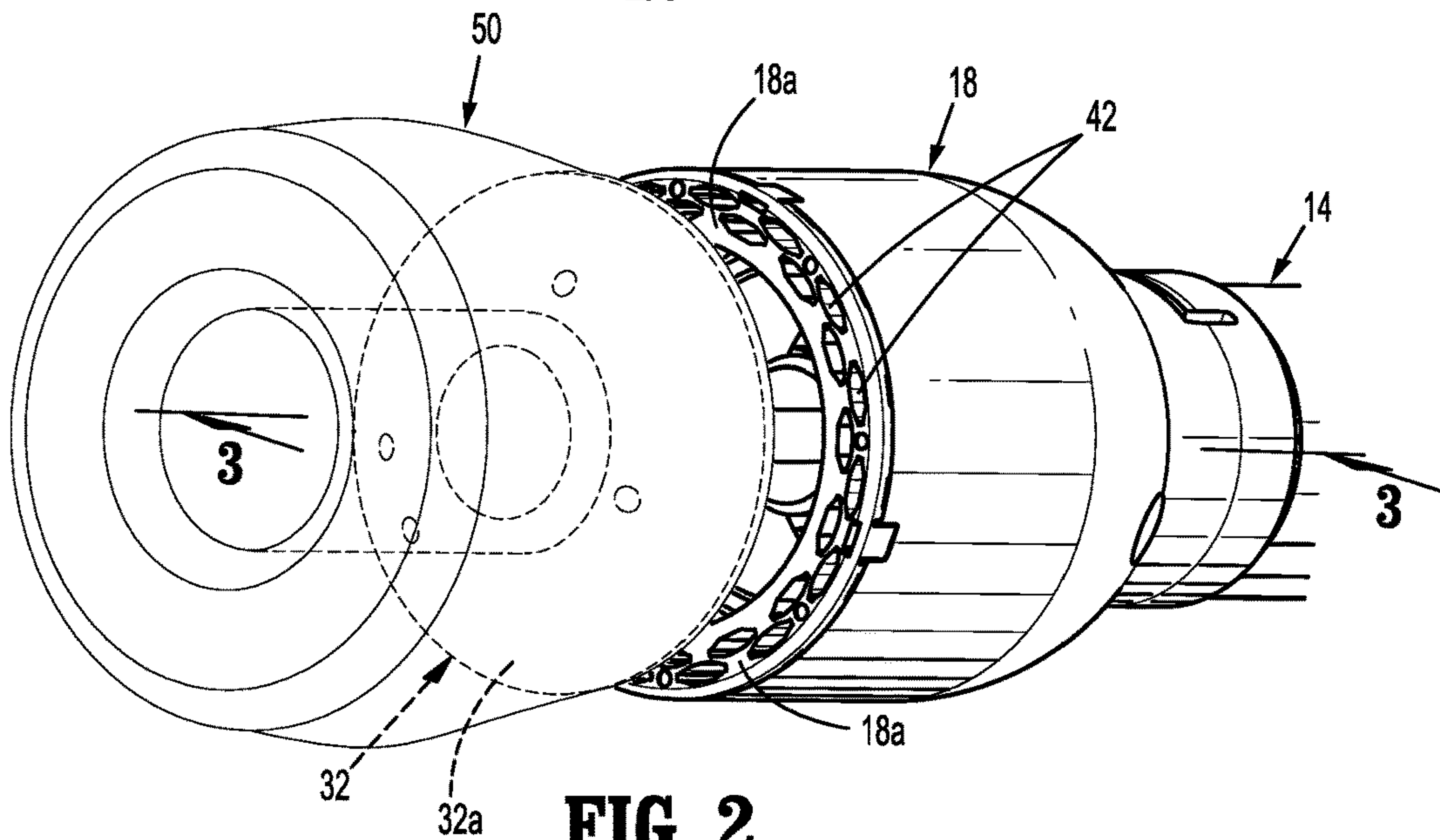
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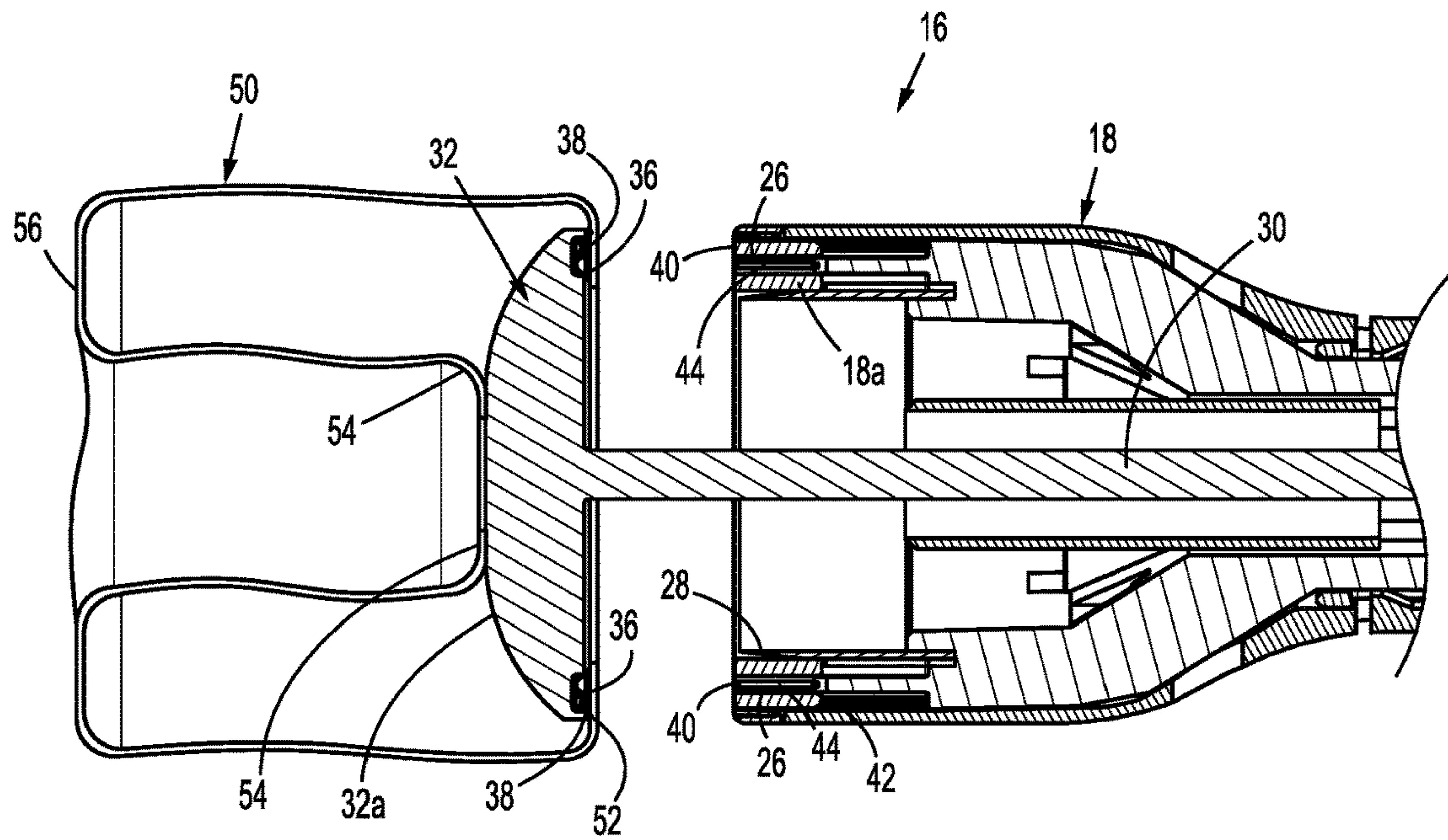


**FIG. 1**

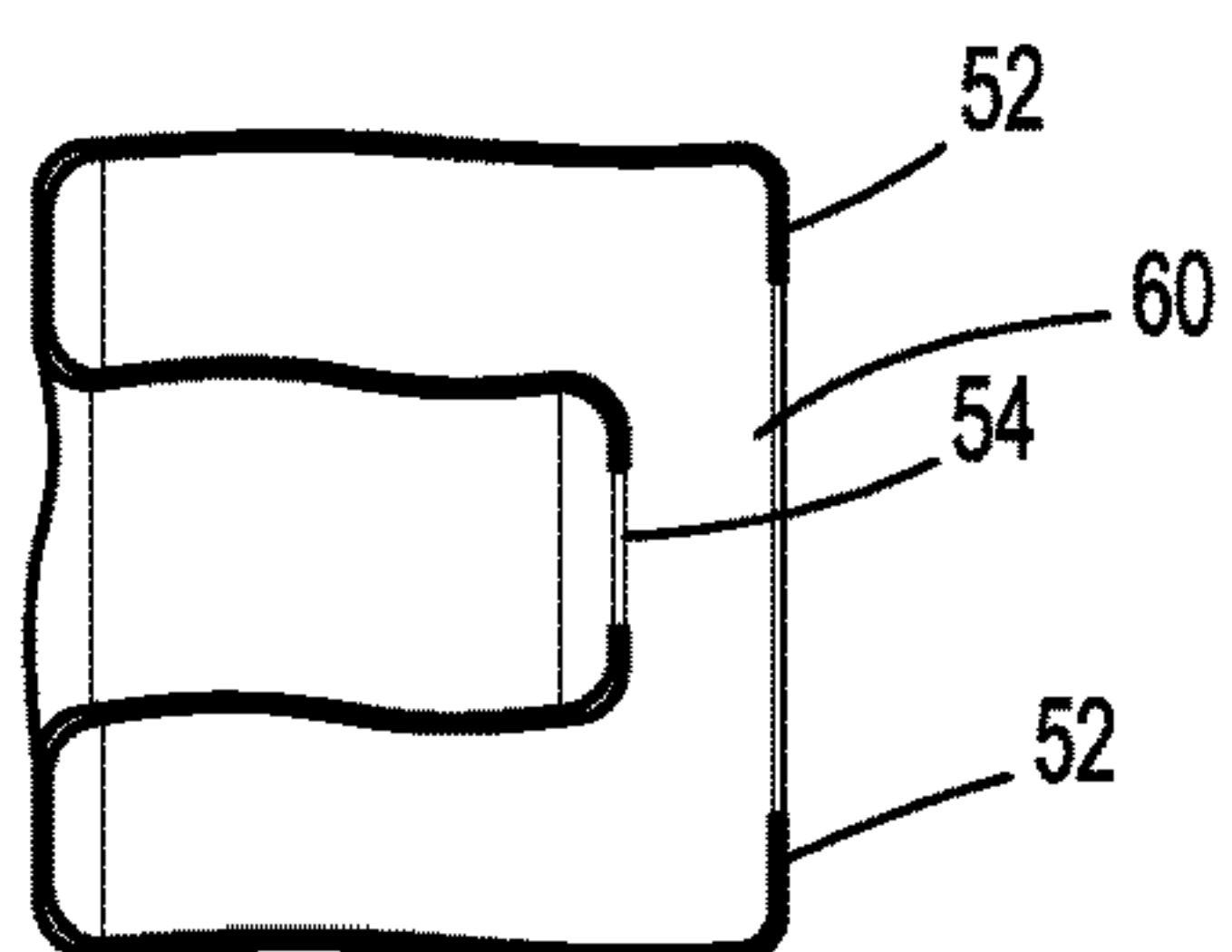
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**FIG. 2**

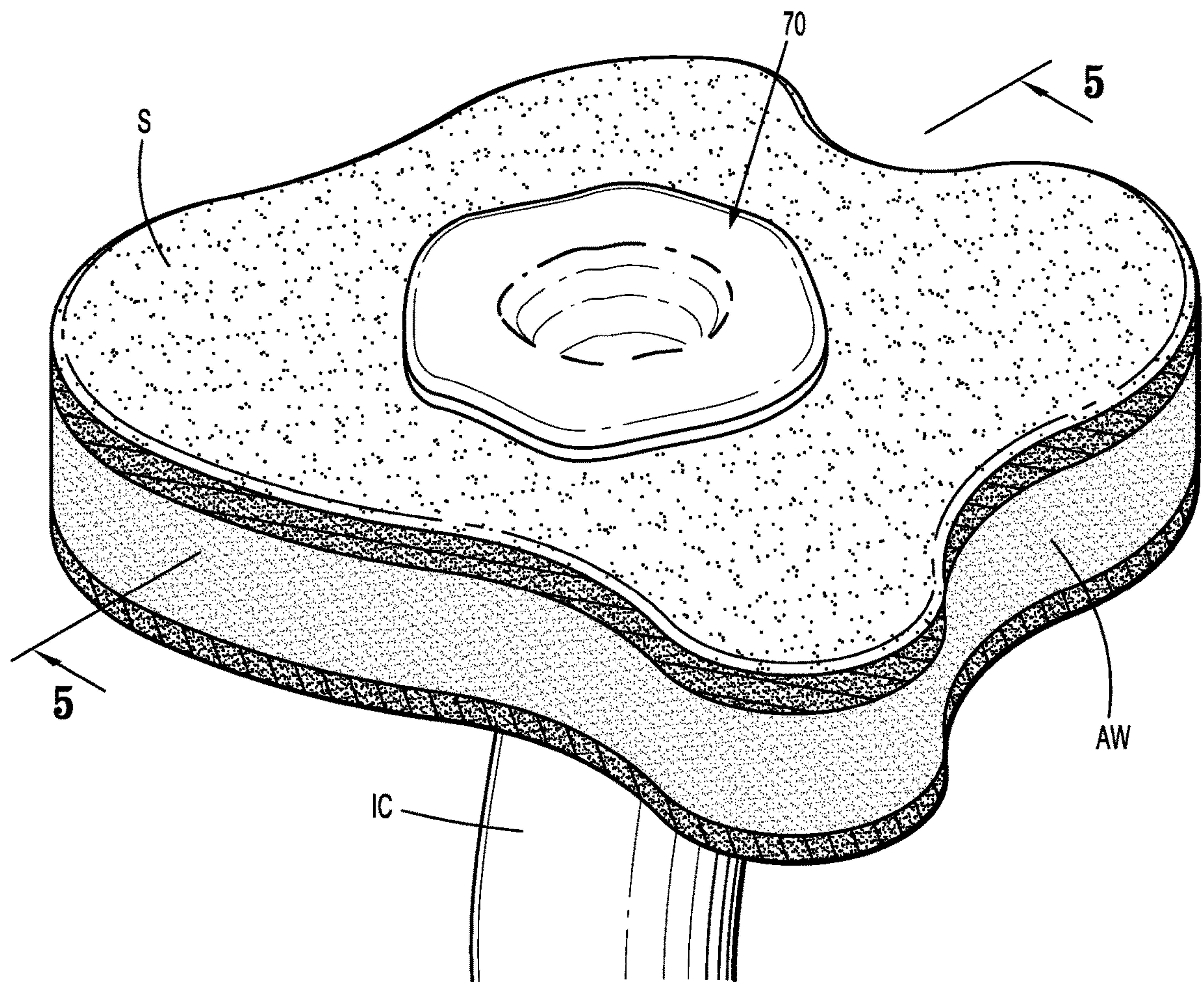


**FIG. 3**



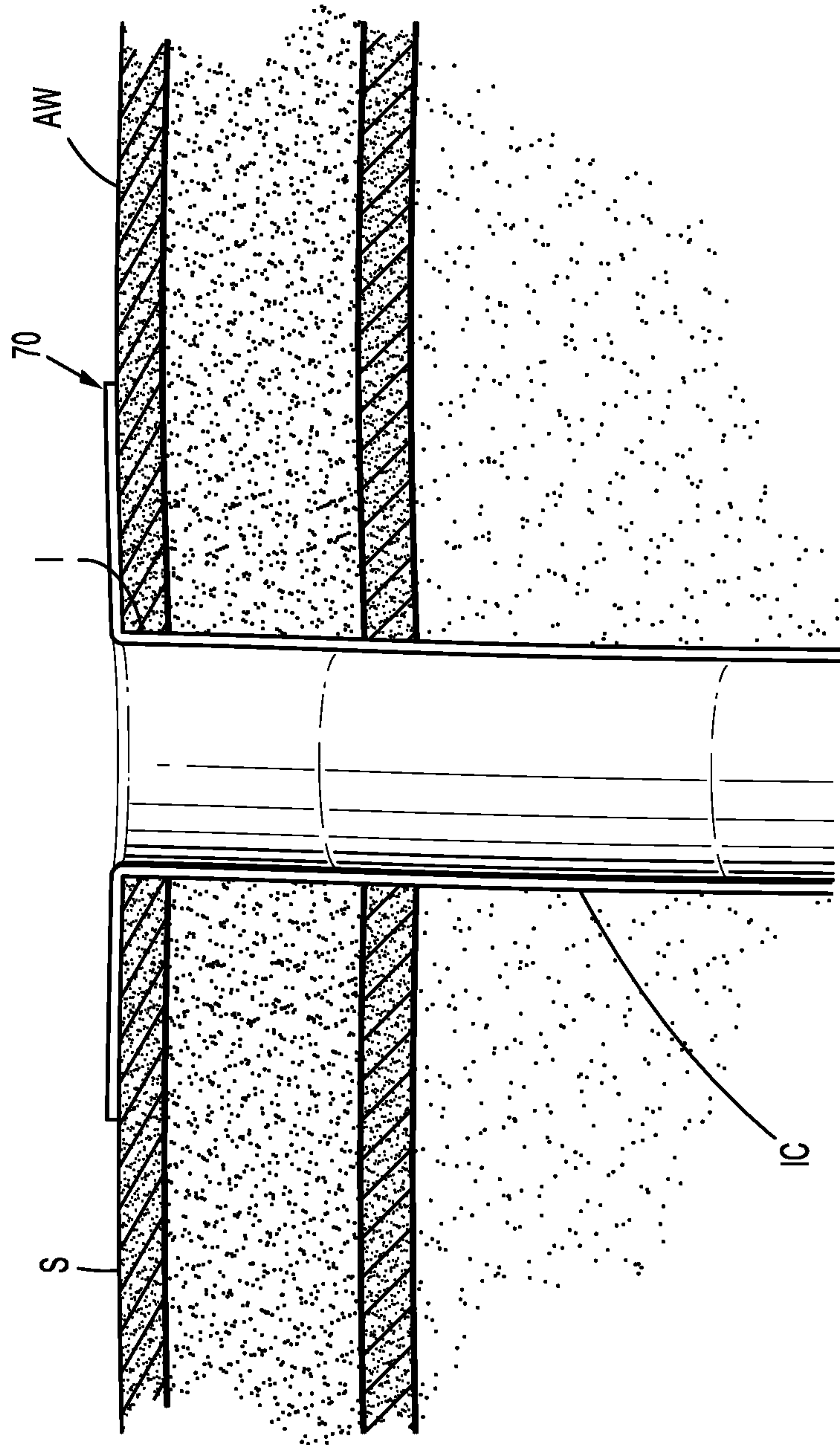
**FIG. 3A**



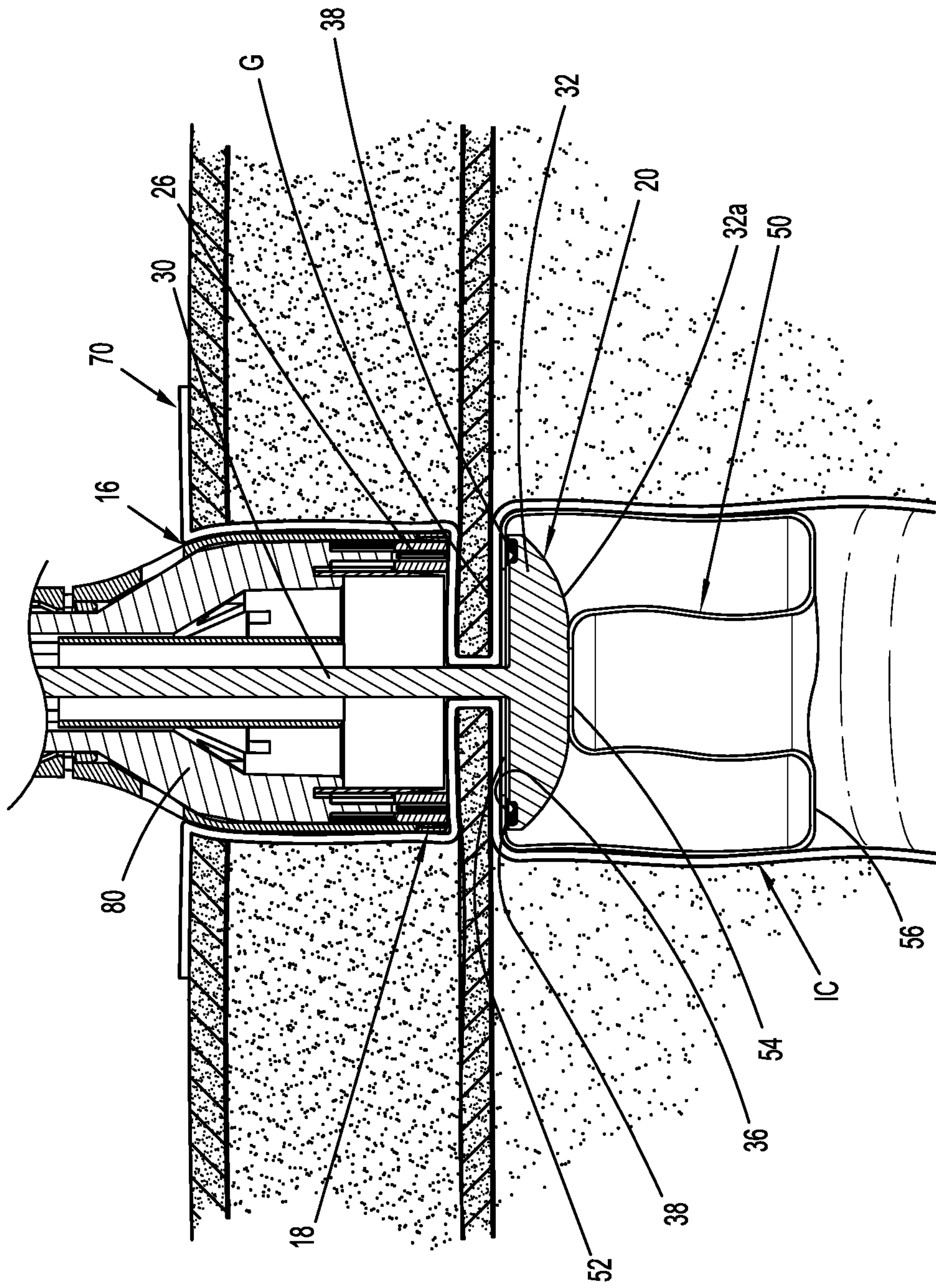


**FIG. 4**



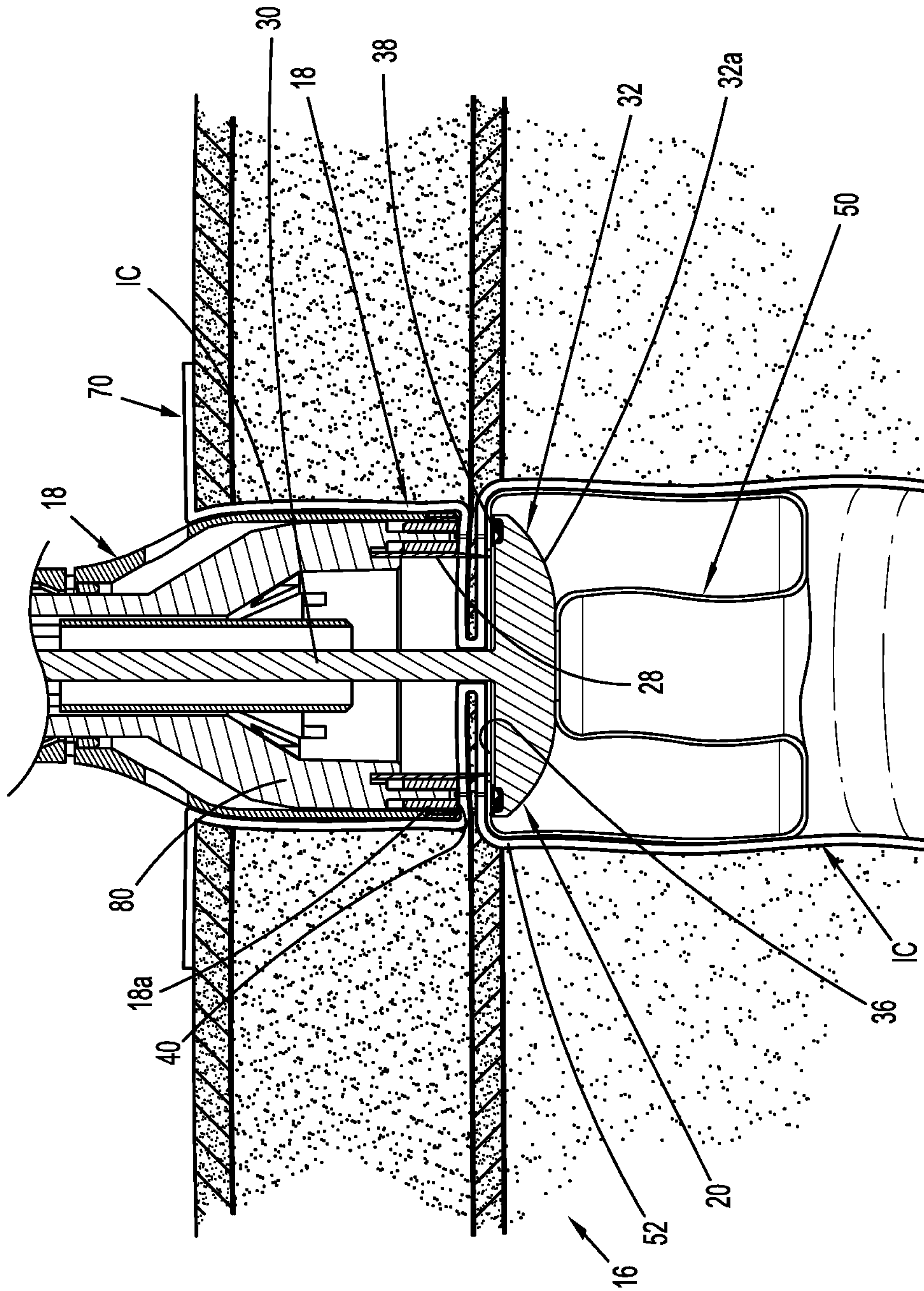


**FIG. 5**



**FIG. 6**





**FIG. 7**

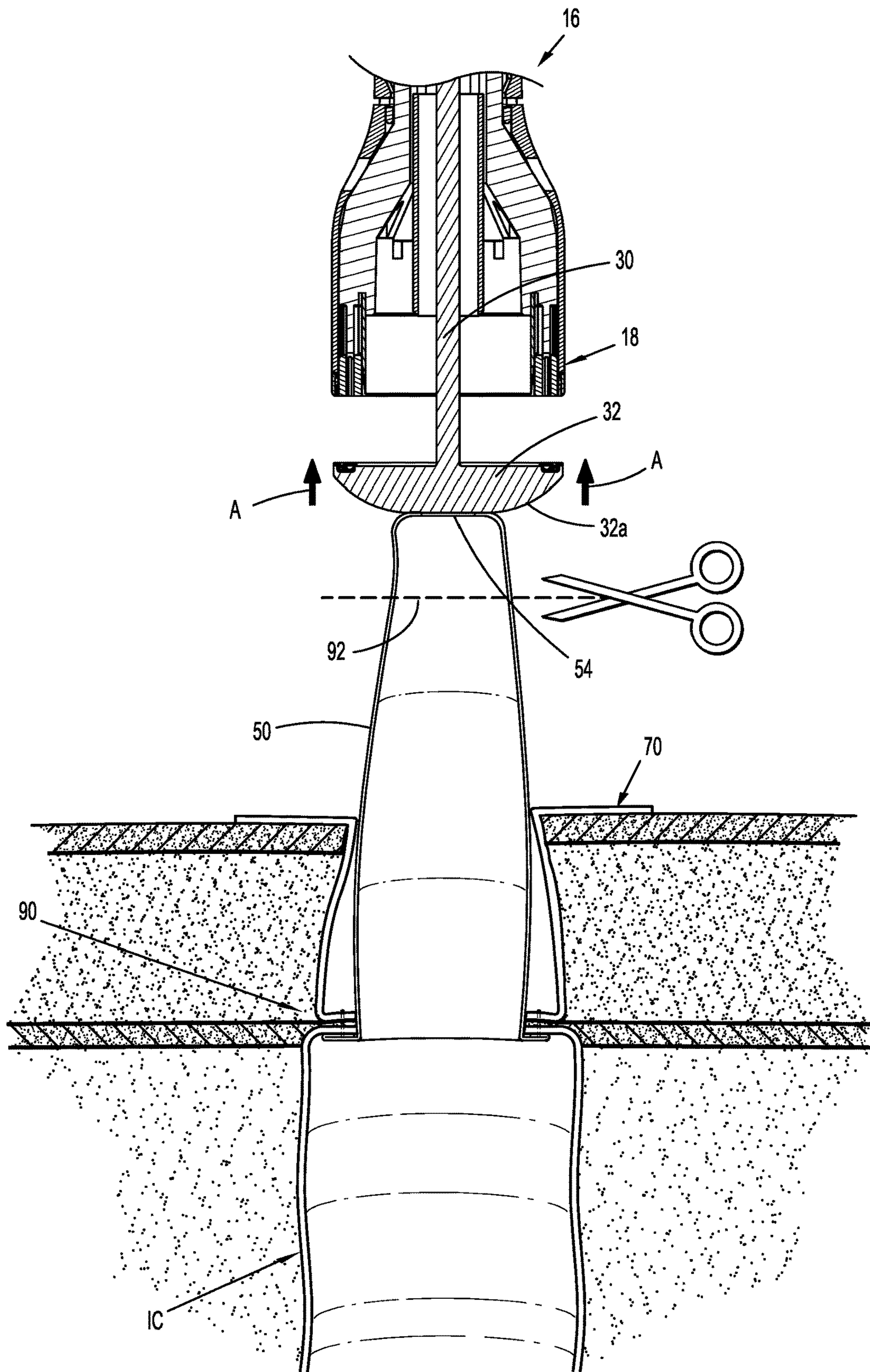
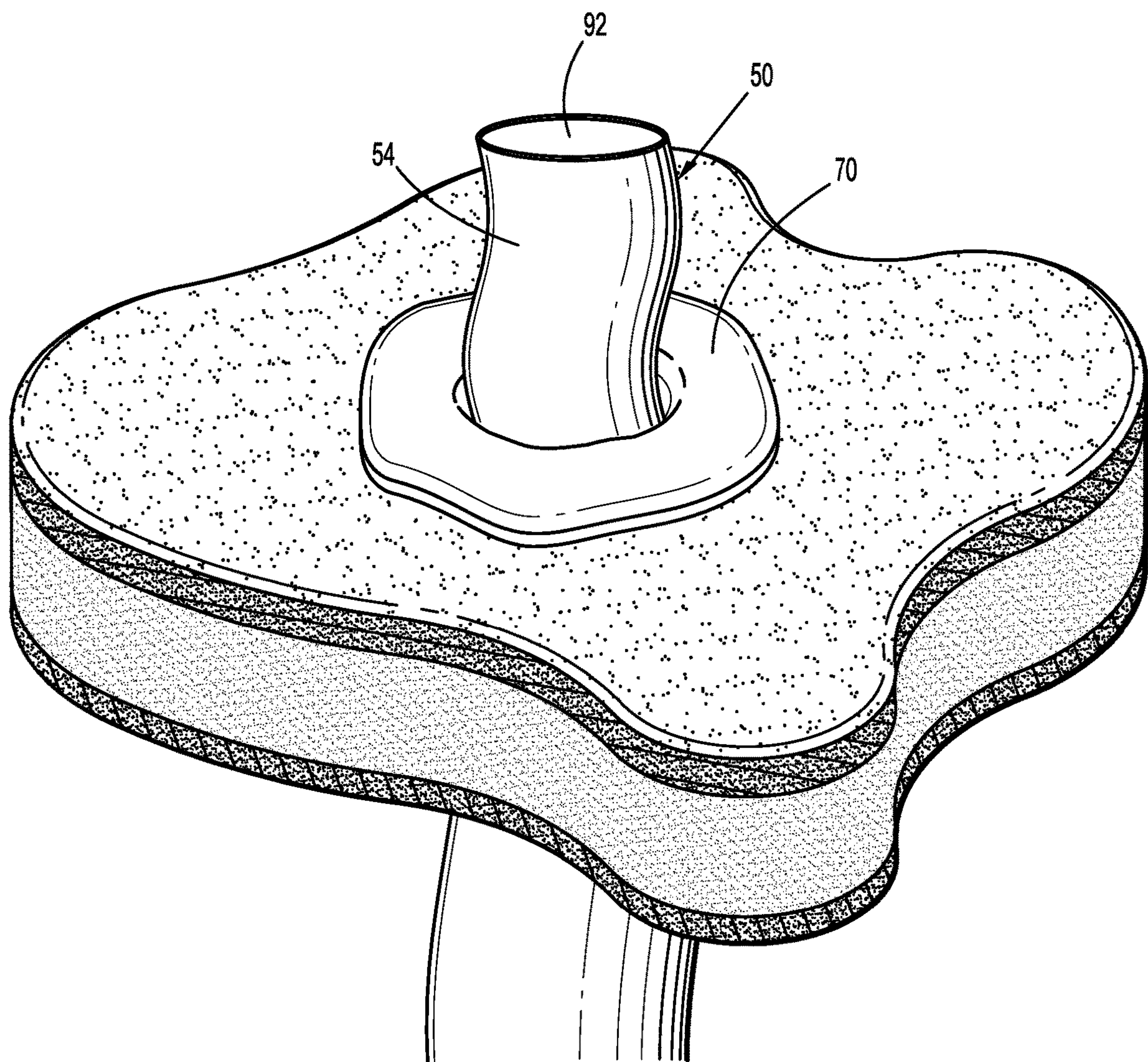


FIG. 8





**FIG. 9**



**1****DEVICE AND METHOD FOR ATTACHMENT  
OF A STOMAL SLEEVE****CROSS-REFERENCE TO RELATED  
APPLICATIONS**

This application claims the benefit of and priority to U.S. Provisional Patent Application Ser. No. 62/581,059 filed Nov. 3, 2017, the entire disclosure of which is incorporated by reference herein.

**BACKGROUND****1. Technical Description**

The present disclosure is directed to a device and method for attaching a stomal sleeve to a stoma and, more particularly, to method of attaching a stomal sleeve to a stoma using a circular stapling device.

**2. Background of Related Art**

During an ostomy procedure, a bisected portion of an intestine is secured to an exterior surface of the abdominal wall to provide internal access into the intestine for collecting fecal matter. The exteriorization of the intestine is called a stoma. Ostomy procedures include ileostomies and colostomies. In an ileostomy procedure, an end of the ileum (i.e., small intestine) is pulled through the abdominal wall and is flared outwardly and sutured to the skin, leaving a smooth, rounded, inside-out ileum as the stoma. In a colostomy procedure, an end or portion of the colon is pulled through the abdominal wall and flared outwardly and fastened (e.g., stitched) to the skin of the patient to form a stoma.

Ostomy surgery is sometimes performed on an emergency basis due to diverticulitis, trauma, radiation complications, volvulus, necrotic bowel, bowel perforation, etc. Children and adults alike may require an ostomy. An ostomy may only be temporary to allow for healing of the bowel or a decrease of inflammation at the surgical site. In some instances an ostomy may be permanent.

Typically, an ostomy bag is secured to the stoma to collect fecal matter from the intestine. If the fecal matter leaks and/or contacts the skin of a patient defining the stoma, the patient's skin can become irritated and/or infected causing the patient pain and discomfort. As such, a need exists for a surgical instrument and method for bypassing an area adjacent the stoma to minimize contact between the patient's skin and fecal matter being collected in the ostomy bag.

**SUMMARY**

In one aspect of the present disclosure, a stapling device includes a tool assembly having an anvil assembly and a shell assembly. The anvil assembly has an anvil shaft and an anvil head having an annular configuration supported on the anvil shaft. The anvil head defines a first tissue contact surface and includes an annular array of staple deforming pockets positioned about the first tissue contacting surface. The shell assembly has a staple cartridge including a second tissue contact surface having an annular array of staple receiving pockets. The tool assembly is movable from an unapproximated position in which the anvil assembly is spaced from the staple cartridge to an approximated position in which the tissue contacting surfaces of the anvil assembly and the staple cartridge are in closer juxtaposed alignment. A stomal sleeve has a tubular configuration, a first end

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portion secured to the first tissue contacting surface of the anvil head radially inwardly of the annular array of staple deforming pockets, and a second end portion secured to a distal surface of the anvil head.

5 In embodiments, the cartridge assembly includes an annular knife that is movable from a retracted position recessed within the staple cartridge to an advanced position in contact with the anvil head.

10 In some embodiments, in the advanced position of the annular knife, the annular knife is positioned to engage the first end portion of the stomal sleeve.

In certain embodiments, the second end portion of the stomal sleeve is closed.

15 In embodiments, the first end portion of the stomal sleeve defines an opening.

In some embodiments, the stomal sleeve is formed from a non-degradable, bio-compatible, pliable material.

In certain embodiments, the stomal sleeve is formed from a polymeric material.

20 In embodiments, the first and second end portions of the stomal sleeve are secured to the anvil head using an adhesive.

In another aspect of the disclosure, a method of attaching a stomal sleeve to a stoma using a circular stapling device includes inserting a tool assembly of the circular stapling device into the stoma with a stomal sleeve attached to an anvil assembly of the tool assembly, wherein the stomal sleeve has a first end portion connected to a first tissue contact surface of the anvil assembly and a second end portion attached to a distal face of an anvil head of the anvil assembly; positioning dermal and intestinal tissue into a tissue gap defined between a staple cartridge of a shell assembly of the tool assembly and the anvil assembly; approximating the shell assembly of the tool assembly with the anvil assembly to clamp the dermal and intestinal tissue between the shell and anvil assemblies; firing the circular stapling device to secure the first end portion of the stomal sleeve to the dermal and intestinal tissue; withdrawing the circular stapling device from the stoma to withdraw a second end portion of the stomal sleeve from the stoma; and disengaging the second end portion of the stomal sleeve from the anvil head of the anvil assembly such that the second end portion of the stomal sleeve is positioned externally of the stoma.

45 In embodiments, the method includes detaching the stomal sleeve from the tissue contact surface of the anvil assembly.

In embodiments, detaching the stomal sleeve from the tissue contact surface of the anvil is effected by an annular knife of the shell assembly.

50 In embodiments, the method includes cutting the second end portion of the stomal sleeve to separate the second end portion of the stomal sleeve from the anvil assembly.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Various embodiments of the presently disclosed stapling device and method for attaching a stomal sleeve to a stoma are described herein below with reference to the drawings, wherein:

FIG. 1 is a side perspective view of one embodiment of the presently disclosed surgical stapling device supporting a stomal sleeve on an anvil assembly of the stapling device;

FIG. 2 is an enlarged view of the indicated area of detail shown in FIG. 1;

65 FIG. 3 is a side cross-sectional view taken along section line 3-3 of FIG. 2;



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FIG. 3A is a side view of the stomal sleeve of the surgical stapling device of FIG. 1;

FIG. 4 is a side perspective view of a stoma of a bowel extending through an opening in an abdomen of a patient;

FIG. 5 is a cross-sectional view taken along section line 5-5 of FIG. 4;

FIG. 6 is a side cross-sectional view of the surgical stapling device of FIG. 1 inserted into the stoma of FIG. 5 prior to full approximation of the stapling device with the stomal sleeve extending from the anvil assembly into the intestine/colon of the patient;

FIG. 7 is side cross-sectional view of the surgical stapling device of FIG. 1 inserted into the stoma of FIG. 5 with the stapling device in an approximated and fired condition and the stomal sleeve extending from the anvil assembly into the intestine/colon of the patient;

FIG. 8 is side cross-sectional view of the surgical stapling device of FIG. 1 as the stapling device is withdrawn from the stoma of FIG. 7 after the stapling device is fired with the stomal sleeve attached to the anvil assembly and extending from the stoma of the patient; and

FIG. 9 is a side perspective view of the stomal sleeve extending from the stoma of the patient after the stomal sleeve is cut and separated from the anvil assembly;

#### DETAILED DESCRIPTION OF EMBODIMENTS

The presently disclosed device and method for attaching a stomal sleeve to a stoma will now be described in detail with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views. In this description, the term “proximal” is used generally to refer to that portion of the device that is closer to a clinician, while the term “distal” is used generally to refer to that portion of the device that is farther from the clinician. In addition, the term clinician is used generally to refer to medical personnel including surgeons, doctors, nurses, and support personnel.

The presently disclosed stapling device has a stomal sleeve secured to an anvil assembly of the stapling device. The stapling device includes a tool assembly having an annular cartridge, an annular anvil assembly that is movable in relation to the annular cartridge between unapproximated and approximated positions, and an annular knife that is moveable into the anvil assembly to cut tissue and disengage one end of the stomal sleeve from attachment with the anvil assembly when the stapling device is fired. The anvil assembly includes an anvil head that defines a tissue contact surface. The stomal sleeve has a tubular configuration having a first end portion secured to the tissue contact surface of the anvil head and a second end portion secured to a distal face of the anvil head.

The presently disclosed method of attaching a stomal sleeve to a stoma includes inserting the tool assembly of the stapling device into the stoma with the stomal sleeve attached to the anvil assembly; positioning dermal and intestinal tissue into a tissue gap defined between the cartridge and anvil assemblies; approximating the cartridge and anvil assemblies to clamp the dermal and intestinal tissue between the cartridge and anvil assemblies; firing the stapling device to secure the first end portion of the stomal sleeve to the dermal and intestinal tissue; withdrawing the stapling device from the stoma to withdraw the second end portion of the stomal sleeve from the stoma; and disengaging the second end portion of the stomal sleeve from the

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anvil head of the anvil assembly such that the second end portion of the stomal sleeve is positioned externally of the stoma.

Particular embodiments of the present disclosure are described below with reference to the accompanying drawings. However, it is to be understood that the disclosed embodiments are merely examples of the disclosure and may be embodied in various forms. Well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to employ the present disclosure in virtually any appropriately detailed structure.

Referring to FIG. 1, the presently disclosed device for attaching a stomal sleeve to a stoma is identified in the figures generally as 10 and includes a handle assembly 12, an elongated body portion 14, and a tool assembly 16. The tool assembly 16 includes an annular shell assembly 18 having an annular staple cartridge 18a and an annular anvil assembly 20 that are movable in relation to each other between an unapproximated or spaced position and an approximated position. The handle assembly 12 includes an approximation knob 22 that is actuatable to move the anvil assembly 20 in relation to the cartridge assembly 18 between the spaced and approximated positions to clamp tissue and a firing trigger 24 that is actuatable to fire staples 26 (FIG. 3) from the staple cartridge 18a into tissue and to advance an annular knife 28 (FIG. 3) into the anvil assembly 20. For a detailed description of an exemplary stapling device suitable for use for attaching a stomal sleeve to a stoma, see U.S. Pat. No. 7,857,187 (“the ’187 patent”) which is incorporated herein by reference in its entirety.

Although the presently disclosed stapling device 10 is shown and described as being a manually powered device, it is envisioned that the stapling device 10 can be an electrically powered device such as described in U.S. Patent Publication No. 2012/0253329 which is incorporated herein by reference in its entirety.

Referring to FIGS. 2 and 3, the anvil assembly 20 includes an anvil shaft 30 (FIG. 3) and an anvil head 32 secured to a distal portion of the anvil shaft 30. The anvil head 32 has a distally facing surface 32a and is attached to a distal portion of the anvil shaft 30 as shown in FIG. 3. Alternatively, the anvil head 32 can be pivotally attached to the distal portion of the anvil shaft 30 such as described in the ’187 patent. A proximal end of the anvil shaft 30 is connected to an approximation mechanism of the device 10. The anvil shaft 30 can be fixedly connected to the approximation mechanism of the device 10 as shown, or, in the alternative, the anvil shaft 30 can be removably connected to the approximation mechanism of the device 10, as described in the ’187 patent. For a more detailed description of the interconnection between the anvil shaft and the approximation mechanism of the device 10, see the ’187 patent.

The anvil head 32 defines a first annular tissue contact surface 36 that includes a plurality of staple deforming pockets 38. The staple deforming pockets 38 (FIG. 3) are disposed in an annular array about the first annular tissue contact surface 36. The staple cartridge 18a includes a second annular tissue contact surface 40 and includes a plurality of staple pockets 42. The staple pockets 42 are positioned in an annular array about the second tissue contact surface 40 and receive staples 44. The cartridge assembly 18 also includes the annular knife 28 that is positioned to engage the anvil head 32 within the annular



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array of staple deforming pockets 38 when the stapling device is fired as discussed in further detail below. For a more detailed description of the cartridge and anvil assemblies, see the '187 patent.

The anvil head 32 supports a stomal sleeve 50 that has a tubular configuration and may be formed from a biocompatible, non-degradable, pliable material, e.g., a polymeric material. In embodiments, the stomal sleeve 50 has a first end portion 52 that is secured to the first tissue contact surface 36 of the anvil head 32 at a location radially inwardly of the annular array of staple deforming pockets 38 and a second end portion 54 that is secured to the distally facing surface 32a of the anvil head 32 such that a central portion 56 of the stomal sleeve 50 is positioned distally of the second end portion 54 of the stomal sleeve 50. The end portions 52, 54 of the stomal sleeve can be secured to the anvil head 32 using adhesives or the like. In embodiments, the first end portion 52 of the stomal sleeve 50 defines an opening 60 (FIG. 3A) and the second end portion 54 is closed. It is envisioned that both of the first and second end portions 52, 54 of the stomal sleeve 50 can initially define an opening or be closed.

Referring to FIGS. 4 and 5, during formation of a stoma 70, a vessel portion, e.g., small or large intestine or colon "IC", is pulled through an incision "I" (FIG. 5) in the abdominal wall "AW" and is everted outwardly and secured to an outer surface of the skin "S", leaving a smooth, rounded, everted vessel portion as the stoma 70. An ostomy bag (not shown) is secured to the stoma 70 to direct fecal matter from within the vessel portion "IC" into the ostomy bag. Formation of the stoma can be performed using a variety of techniques and devices and does not form part of the presently disclosed method. Embodiments of a stapling device and method for forming a stoma are described in U.S. application Ser. No. [203-11280] which is incorporated herein in its entirety by reference.

Referring to FIG. 6, after the stoma 70 is created, in order to attach the stomal sleeve 50 to a position within the vessel portion "IC", the tool assembly 16 of the stapling device 10 is inserted through the stoma 70 with the cartridge assembly 18 and anvil assembly 20 in an unapproximated position. In this position, the stomal sleeve 50 is supported on the anvil head 32 and extends into the vessel portion "IC" distally of the anvil head 32. With the tool assembly 16 positioned within the vessel portion "IC", tissue including a portion of the vessel portion "IC" is drawn into the tissue into tissue gap "G" defined between the staple cartridge 18a and the anvil assembly 20. As discussed above, the stomal sleeve 50 has a first end portion 52 that is secured to the first tissue contact surface 36 of the anvil head 32 at a location radially inwardly of the annular array of staple deforming pockets 38 and a second end portion 54 that is secured to a distal face 32a of the anvil head 32.

Referring to FIG. 7, after tissue has been drawn into the tissue gap "G" (FIG. 6), the stapling device 10 is approximated to clamp tissue between the cartridge assembly 18 and the anvil assembly 20. More specifically, when the tool assembly 16 is moved to the approximated position, tissue including a portion of the vessel portion "IC" is clamped between the tissue contact surface 36 of the anvil head 32 and the tissue contact surface 40 of the staple cartridge assembly 18a. As shown, the first end portion 52 of the stomal sleeve 50 is also clamped between the tissue and the contact surface 36 of the anvil head 32.

When the stapling device 10 (FIG. 1) is fired, a pusher 80 of the stapling device 10 is advanced through the cartridge assembly 18 to drive staples 26 (FIG. 6) from the staple

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cartridge 18a through the tissue including the vessel portion "IC". Simultaneously, the annular knife 28 is advanced towards the anvil head 32 to cut the tissue and the first end portion 52 of the stomal sleeve 50 radially inwardly of the staple deforming pockets 38. When the annular knife 28 cuts through the first end portion 52 of the stomal sleeve 50, the first end portion 52 of the stomal sleeve 50 is separated from the anvil head 32 and stapled to the vessel portion "IC" and surrounding tissue (FIG. 8).

Referring to FIG. 8, after the tool assembly 16 of the stapling device 10 is unapproximated to release the clamped tissue from between the cartridge assembly 18 and the anvil assembly 20, the stapling device 10 (FIG. 1) can be withdrawn in the direction indicated by arrows "A" in FIG. 8 to withdraw the tool assembly 16 from the stoma 70. As discussed above, the second end portion 54 of the stomal sleeve 50 is attached to the distal face 32a of the anvil head 32. Thus, as the tool assembly 16 is withdrawn from the stoma 70, the second end portion 54 of the stomal sleeve 50 is pulled through the stoma 70 to a position externally of the stoma 70 such that the stomal sleeve 50 defines an internal liner from the stapling location 90 within the vessel portion "IC" through the stoma 70.

Referring also to FIG. 10, when the stomal sleeve 50 is positioned externally of the stoma 50, the second end portion 54 of the stomal sleeve 50 can be separated from the anvil head 32 to define an opening or mouth 92 adjacent the second end portion 54 of the stomal sleeve 50. In embodiments, the second end portion 54 of the stomal sleeve 50 is closed and is separated from the anvil head 32 by cutting the second end portion 54 using a scissor 96 (FIG. 9) along a cut line "CL". As illustrated, in this position, the stomal sleeve 50 provides an insulative barrier from a position within the vessel portion "IC" through the stoma 70. It is also envisioned that the second end portion 54 of the stomal sleeve 50 may define an opening and be secured to the anvil head 32 by an adhesive. In this embodiment, instead of cutting the second end portion 54 of the stomal sleeve 50, the second end portion 54 of the stomal sleeve 50 can be separated from the distal surface 32a of the anvil head 32 by pulling the second end portion 54 in a direction away from the anvil head 32 to disengage the second end portion 54 from the adhesive on the anvil head 32. Other methods of releasably securing the second end portion 54 of the stomal sleeve 50 to the anvil head 32 are envisioned.

Persons skilled in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments. It is envisioned that the elements and features illustrated or described in connection with one exemplary embodiment may be combined with the elements and features of another without departing from the scope of the present disclosure. As well, one skilled in the art will appreciate further features and advantages of the disclosure based on the above-described embodiments. Accordingly, the disclosure is not to be limited by what has been particularly shown and described, except as indicated by the appended claims.

What is claimed is:

1. A stapling device comprising;

a tool assembly including an anvil assembly and a shell assembly, the anvil assembly having an anvil shaft and an anvil head having an annular configuration supported on the anvil shaft, the anvil head defining a first tissue contact surface and including an annular array of staple deforming pockets positioned about the first tissue contacting surface, the shell assembly including



a staple cartridge defining a second tissue contact surface having an annular array of staple receiving pockets, the tool assembly being movable from an unapproximated position in which the anvil assembly is spaced from the staple cartridge to an approximated position in which the tissue contacting surfaces of the anvil assembly and the staple cartridge are in closer juxtaposed alignment; and

a stomal sleeve having a tubular configuration, the stomal sleeve having a first end portion secured to the first tissue contacting surface of the anvil head radially inwardly of the annular array of staple deforming pockets with a first adhesive and a second end portion secured to a distal surface of the anvil head with a second adhesive.

2. The stapling device of claim 1, wherein the shell assembly includes an annular knife that is movable from a retracted position recessed within the staple cartridge to an advanced position in contact with the anvil head.

3. The stapling device of claim 2, wherein in the advanced position of the annular knife, the annular knife is positioned to engage the stomal sleeve at a location adjacent the first end portion.

4. The stapling device of claim 3, wherein the second end portion of the stomal sleeve is closed.

5. The stapling device of claim 4, wherein the first end portion of the stomal sleeve defines an opening.

6. The stapling device of claim 3, wherein the stomal sleeve is formed from a non-degradable, bio-compatible, pliable material.

7. The stapling device of claim 5, wherein the stomal sleeve is formed from a polymeric material.

\* \* \* \* \*